

USSN 10/027,349
Amendment filed April 21, 2004

Amendments to the Claims

This listing of claims will replace all prior versions of the claims in the application:

Listing of Claims:

Claims 1 – 37 are canceled.

Claim 38. (currently amended) A pharmaceutical composition, comprising:

- (a) guanfacine;
- (b) ~~Hydroxypropyl Methylcellulose~~ hydroxypropyl methylcellulose;
- (c) ~~Ammonio Methacrylate Copolymer~~ ammonio methacrylate copolymer;
- (d) microcrystalline cellulose;
- (e) a methacrylic acid copolymer;
- (f) glyceryl behenate;
- (g) ~~Fumaric Acid~~ fumaric acid;
- (h) ~~Lactose Monohydrate~~ lactose monohydrate;
- (i) povidone; and
- (j) ~~Crospovidone Granulated Blend~~ crospovidone granulated blend.

Claim 39. (currently amended) A pharmaceutical composition, comprising:

- (a) ~~Guanfacine~~ guanfacine hydrochloride;
- (b) ~~Hydroxypropyl Methylcellulose~~ hydroxypropyl methylcellulose;
- (c) ~~Ammonio Methacrylate Copolymer~~ ammonio methacrylate copolymer;
- (d) microcrystalline cellulose;

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- (e) a methacrylic acid polymer;
- (f) glyceryl behenate;
- (g) ~~Fumaric Acid~~, fumaric acid;
- (h) ~~Lactose Monohydrate~~ lactose monohydrate;
- (i) ~~Povidone~~ povidone; and
- (j) ~~Crospovidone Granulated Blend~~ crospovidone granulated blend.

Claim 40 (currently amended) A method for treating an attention deficit disorder or attention deficit with hyperactivity disorder in a patient, comprising administering to said patient a the composition of Claim 4 comprising

- (a) at least one pharmaceutically active agent that is pH dependent, said pharmaceutically active agent being guanfacine or guanfacine hydrochloride;
- (b) at least one non-pH dependent sustained release agent selected from the group consisting of ethylcellulose, cellulose acetate, vinyl acetate/vinyl chloride copolymers, acrylate/methacrylate copolymers, polyethylene oxide, hydroxypropyl methylcellulose, carageenan, alginic acid and salts thereof, hydroxyethyl cellulose, hydroxypropyl cellulose, karaya gum, acacia gum, tragacanth gum, locust bean gum, guar gum, sodium carboxymethyl cellulose, methyl cellulose, beeswax, carnauba wax, cetyl alcohol, hydrogenated vegetable oils, and stearyl alcohol;
and

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- (c) at least one pH dependent agent that increases the rate of release of said at least one pharmaceutically active agent from a tablet dosage form at a pH in excess of 5.5;

which is given in an amount effective to treat said attention deficit disorder or attention deficit with hyperactivity disorder in said patient.

Claim 41. (currently amended) A method of reducing the likelihood of side effects associated with the administration of guanfacine, comprising administering to a patient a therapeutically effective amount of a the composition of Claim 1 comprising

- (a) at least one pharmaceutically active agent that is pH dependent , said pharmaceutically active agent being guanfacine or guanfacine hydrochloride;
- (b) at least one non-pH dependent sustained release agent selected from the group consisting of ethylcellulose, cellulose acetate, vinyl acetate/vinyl chloride copolymers, acrylate/methacrylate copolymers, polyethylene oxide, hydroxypropyl methylcellulose, carageenan, alginic acid and salts thereof, hydroxyethyl cellulose, hydroxypropyl cellulose, karaya gum, acacia gum, tragacanth gum, locust bean gum, guar gum, sodium carboxymethyl cellulose, methyl cellulose, beeswax, carnauba wax, cetyl alcohol, hydrogenated vegetable oils, and stearyl alcohol;
and

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(c) at least one pH dependent agent that increases the rate of release of said at least one pharmaceutically active agent from a tablet dosage form at a pH in excess of 5.5.

42. (new) The method of claim 40, wherein said at least pH-dependent agent is at least one polymer that swells at a pH in excess of 5.5.

43. (new) The method of claim 42, wherein said at least one polymer that swells at a pH in excess of 5.5 is selected from acrylic acid polymers, sodium alginate, carrageenan, alginic acid, pectin, or sodium carboxymethylcellulose.

44. (new) The method of claim 40, wherein said at least one pH-dependent agent is at least one enteric agent.

45. (new) The method of claim 44, wherein said enteric agent is selected from cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polvinyl acetate phthalate, methacrylic acid copolymers, cellulose acetate trimellitate, hydroxypropyl methylcellulose acetate, succinate, shellac, or zein.

46. (new) The method of claim 41, wherein said at least pH-dependent agent is at least one polymer that swells at a pH in excess of 5.5.

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47. (new) The method of claim 46, wherein said at least one polymer that swells at a pH in excess of 5.5 is selected from acrylic acid polymers, sodium alginate, carrageenan, alginic acid, pectin, or sodium carboxymethylcellulose.

48. (new) The method of claim 41, wherein said at least one pH-dependent agent is at least one enteric agent.

49. (new) The method of claim 48, wherein said enteric agent is selected from cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, methacrylic acid copolymers, cellulose acetate trimellitate, hydroxypropyl methylcellulose acetate, succinate, shellac, or zein.